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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,299	01/31/2002	Leroy E. Hood	066661-0041	2563

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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/062,299	HOOD ET AL.	
	Examiner	Art Unit	
	Carolyn L. Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *1-21 and 36-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and remarks, filed 12/27/07, are acknowledged. Amended claims 22, 24, and 30 are acknowledged. Claims 1-21 and 36-49 remain withdrawn as being drawn to non-elected subject matter.

Applicant's arguments, filed 12/27/07, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 22-35 are herein under examination.

Claim Rejections - 35 USC § 112, Second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites "said determination in step (c)" which lacks clarity. Step c) is a comparing step, making it unclear if the determination is from step (b) or (d). Clarification of this issue via clearer claim wording is requested. Claim 23 is also rejected due to its dependency from claim 22. This rejection is necessitated by amendment.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Stoughton et al. (P/N 6,132,969).

This rejection is maintained and reiterated for reasons of record.

Stoughton et al. disclose laboratory and computer methods for testing and confirming how well a network model represents a biological pathway in a biological system (abstract) wherein the biological pathway in a biological system represents a biochemical system. Stoughton et al. disclose obtaining measurements for drug and pathway responses (col. 52, lines 56-62) and perturbing and monitoring components in a network model (col. 53, lines 38-64) which represents physically perturbing a component, as stated in instant claim 22. Stoughton et al. disclose the network comprises logical operators relating to input cellular constituents (components), such as mRNA and proteins, to output classes of cellular constituents which are affected by the pathway (abstract), which represents assigning a cellular function to components (col. 10, line 61 to col. 11, line 3), as stated in instant claims 22, 24, and 30. Stoughton et al. disclose use of positionally addressable transcript microarrays which are ordered and reproducible matrices for easy comparison with each other and capable of containing single sites per specific mRNA (col. 45, lines 17-39, col. 46, lines 58-67, and col. 51, lines 39-49) and

making measurements of graded drug exposure and of graded levels of modification/perturbation control parameters and other methods that statistically sample cDNA pools (col. 52, first and fourth paragraphs) and normalizing relative changes (col. 4, second and third paragraphs) wherein the microarrays inherently involve mRNA locations containing x and y dimensions (multidimensional coordinate points with statistically characterized data elements) for components of a physically perturbed system including values for n parameters integrated into n-dimensional space (i.e. measurements of drug exposure and levels of perturbation in a 2-dimensional microarray space) corresponding to the number of measured components within the biochemical system, as stated in instant claims 22, 24, and 30. Stoughton et al. disclose comparing measured relative changes of each cellular constituent to defined relative changes (col. 4, second paragraph) and Figure 9 illustrates positioning "0" state over "1" state (col. 28, lines 3-22) which represents comparison to a reference region, as stated in instant claims 22, 24, and 30. Stoughton et al. disclose comparing relative changes in the biological system in response to perturbations of the network (abstract and col. 8, lines 40-41 and col. 8, line 64 to col. 9, line 12). Stoughton et al. disclose comparing relative changes between two states in a biological system (col. 3, lines 15-20) including normal reference "0" and perturbed expression "1" states (col. 7, lines 50-64 and col. 8, lines 34-52), which represents comparison to a reference expression region, as stated in instant claims 22, 24, 27, 30, and 33. Stoughton et al. disclose predicting how output classes behave in response to the chosen experiments by finding measures (multidimensional coordinate points) of relative change of cellular constituents (components) and finding goodnesses of fit ("the conformity between an experimental result and theoretical expectation", according to Merriam-Webster's online dictionary) of each observed component to

an output class (reference data element region) based on strongest correlations (abstract), which represent a linkage to the perturbed biochemical network. Stoughton et al. disclose analyzing a scanned image by using an image grid program that creates a spreadsheet of the average hybridization at each wavelength at each site (col. 51, lines 1-5) which represents output. Stoughton et al. disclose the relative abundance of mRNA is scored as a perturbation if there is a difference of the two sources of mRNA tested (col. 51, lines 14-27) and outputting values of the network (abstract and col. 3, second and third paragraphs) which represents determining if the multidimensional coordinate point is within or outside the reference region and a difference (outside the region) is indication of linkage to a perturbation as well as providing an output, as stated in instant claims 22, 24, and 30. Stoughton et al. disclose assigning a cellular function to components of a network or pathway (col. 10, line 58 to col. 11, line 3), as stated in instant claims 22, 24, and 30. Stoughton et al. disclose determining the overall goodness of fit of the network model (network-associated expression region) from the individual goodnesses of fit of each observed component (abstract), which also represents determining the multidimensional coordinate point representing a data element of a set of components in a network, as stated in instant claim 24. Stoughton et al. disclose observing a system's response to known inputs via gene expression and/or protein abundances (col. 2, first paragraph), as stated in instant claims 23, 26, 28, 29, 32, 34, and 35. Stoughton et al. disclose the biological system as a cell, organism, and patient (col. 5, line 67 to col. 6, line 1) which represents the biochemical system, as stated in instant claims 25 and 31.

Thus, Stoughton et al. anticipate the limitations in claims 22-35.

Applicants summarize the rejection. Applicants argue that the Office has failed to establish that each and every claim element is expressly or inherently described in Stoughton et al., including new limitations "statistically characterized data element" and "n parameters integrated into n-dimensional space". This statement is found unpersuasive as Stoughton et al. disclose use of positionally addressable transcript microarrays which are ordered and reproducible matrices for easy comparison with each other and capable of containing single sites per specific mRNA (col. 45, lines 17-39, col. 46, lines 58-67, and col. 51, lines 39-49) and making measurements of graded drug exposure and of graded levels of modification/perturbation control parameters and other methods that statistically sample cDNA pools (col. 52, first and fourth paragraphs) and normalizing relative changes (col. 4, second and third paragraphs) wherein the microarrays inherently involve mRNA locations containing x and y dimensions (multidimensional coordinate points with statistically characterized data elements) for components of a physically perturbed system including values for n parameters integrated into n-dimensional space (i.e. measurements of drug exposure and levels of perturbation on a 2-dimensional array space) corresponding to the number of measured components within the biochemical system. It is noted that "n" is not limited to any particular number and can even be zero. It is noted that one broad and reasonable interpretation of "integrate" is to unite or incorporate. Applicants mention Figures 1 and 2 of the instant application and summarize multidimensional coordinate points. Applicants argue that a data element cannot be a physical location like on a microarray spot. This argument is found unpersuasive as Stoughton et al. disclose making measurements of graded drug exposure and of graded levels of modification/perturbation control parameters and other methods that statistically sample cDNA

pools (col. 52, first and fourth paragraphs) and normalizing relative changes (col. 4, second and third paragraphs) of these spots which represent multidimensional coordinate points. Applicants again argue that Stoughton et al. do not recite n parameters integrated in n-dimensional space which has already been found unpersuasive for reasons given above.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

March 11, 2008

/Carolyn Smith/
Primary Examiner
AU 1631